General

Guideline Title

Adjuvant and salvage radiotherapy after prostatectomy: ASTRO/AUA guideline.

Bibliographic Source(s)

Valicenti RK, Thompson I Jr, Albertsen P, Davis BJ, Goldenberg SL, Wolf JS, Sartor O, Klein E, Hahn C, Michalski J, Roach M III, Faraday MM. Adjuvant and salvage radiotherapy after prostatectomy: AUA/ASTRO guideline. Fairfax (VA): American Society for Radiation Oncology (ASTRO); 2013 Apr. 82 p. [334 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Body of evidence strength (A-C) and Nomenclature Linking Statement Type to Level of Certainty and Evidence Strength (Standard, Recommendation, Option, Clinical Principle, and Expert Opinion) are defined at the end of the "Major Recommendations" field.

Guideline Statement 1

Patients who are being considered for management of localized prostate cancer with radical prostatectomy (RP) should be informed of the potential for adverse pathologic findings that portend a higher risk of cancer recurrence and that these findings may suggest a potential benefit of additional therapy after surgery. Clinical Principle

Discussion. Patients should be counseled before RP that certain pathology findings at prostatectomy are associated with higher risks for cancer recurrence. These findings include positive surgical margins, the presence of seminal vesicle invasion (SVI), and extraprostatic extension (EPE).

Patients also should be informed that if these adverse pathological features are detected, then additional therapy after surgery, such as radiotherapy (RT), may be beneficial.

Guideline Statement 2

Patients with adverse pathologic findings including SVI, positive surgical margins, and EPE should be informed that adjuvant radiotherapy (ART), compared to RP only, reduces the risk of biochemical (prostatic specific antigen [PSA]) recurrence, local recurrence, and clinical progression of cancer. They should also be informed that the impact of ART on subsequent metastases and overall survival is less clear; one of two randomized controlled trials that addressed these outcomes indicated a benefit but the other trial did not demonstrate a benefit. Clinical Principle

Discussion. Patients with adverse pathologic findings at prostatectomy should be counseled regarding the most up-to-date findings from the randomized controlled trials that have evaluated the use of ART. This counseling should emphasize that high-quality evidence indicates that the use of ART in patients with adverse pathological findings reduces the risk of biochemical recurrence, local recurrence, and clinical progression of cancer. Patients also should be informed that the impact of ART on subsequent metastases and overall survival is less clear, with benefits reported in one of two trials with long-term data on these outcomes. Clinicians also should counsel patients regarding the potential benefits and risks/burdens of the available treatment alternatives if biochemical recurrence, local recurrence, and/or clinical progression occur.

Guideline Statement 3

Physicians should offer ART to patients with adverse pathologic findings at prostatectomy including SVI, positive surgical margins, or EPE because of demonstrated reductions in biochemical recurrence, local recurrence, and clinical progression. Standard

Discussion. (Evidence strength – Grade A; Benefits outweigh risks/burdens). The Panel is fully aware that the apparent benefits associated with ART are the result, in part, of a subset of patients treated who never would have presented with recurrence. For this reason, the Panel emphasizes that ART should be offered to all patients at high risk of recurrence because of adverse pathological features. By "offered," the Panel means that the patient, his family, and the multi-disciplinary treatment team should engage in a shared decision-making process in which the patient is advised to consider the possibility of additional treatment (i.e., RT). Whether ART is likely to benefit a particular patient and should be administered is a decision best made by the multidisciplinary treatment team and the patient with full and thoughtful consideration of the patient's history, current functional status, values, and preferences, and his tolerance for the potential toxicities and quality of life effects of RT.

In the context of offering ART to patients, it should be emphasized that there is less certainty regarding potential benefits in terms of preventing metastatic recurrence and improving overall survival.

The Panel also notes that RT should be offered to patients with adverse pathology detected at prostatectomy who have a persistent post-prostatectomy PSA level.

Guideline Statement 4

Patients should be informed that the development of a PSA recurrence after surgery is associated with a higher risk of development of metastatic prostate cancer or death from the disease. Congruent with this clinical principle, physicians should regularly monitor PSA after RP to enable early administration of salvage therapies if appropriate. Clinical Principle

Discussion. PSA levels drawn following a RP should be undetectable. An increasing PSA level suggests the presence of residual disease and frequently heralds the eventual development of symptomatic metastases and death from prostate cancer.

Patients should be informed of the relationship between PSA recurrence post-surgery and the probability of metastatic recurrence and death from prostate cancer.

Guideline Statement 5

Clinicians should define biochemical recurrence as a detectable or rising PSA value after surgery that is $\geq$0.2 ng/ml with a second confirmatory level $\geq$0.2 ng/ml. Recommendation

Discussion. (Evidence strength – Grade C; Benefits outweigh risks/burdens). Patients who have had a prostatectomy should be informed that a PSA value of 0.2 ng/ml or higher that has been confirmed by a second elevated PSA value constitutes evidence of a biochemical recurrence. The presence of a biochemical recurrence necessitates a thorough discussion of the available alternatives for salvage therapy, including the use of RT and other types of therapy, and is sufficient to trigger the administration of salvage therapies. The Panel further notes that there is no evidence to suggest a threshold above which RT is ineffective.

The Panel notes that recurrences can be identified earlier and at much lower PSA levels (e.g., 0.07 ng/mL or less) using ultra-sensitive PSA assays. In addition, even more sensitive assays may add further clarity as to whether patients are at increased risk for clinical failure.

The Panel notes that the decision to initiate salvage therapies is best made by the clinician who has full knowledge of a specific patient's pathology findings, risk factors, family history, preferences, and values in consultation with that patient and with full discussion of the potential benefits and risks of treatment. In the era of ultrasensitive PSA assays, a detectable PSA that is confirmed and rising may be an appropriate trigger for salvage therapy, particularly in patients who are at high risk for recurrence and/or who have other evidence of potential progression.

Guideline Statement 6

A restaging evaluation in the patient with a PSA recurrence may be considered. Option

Discussion. (Evidence strength – Grade C; Balance between benefits and risks/burdens uncertain). In the patient with evidence of recurrence manifested as a detectable or rising PSA, determining the site of recurrence (local vs. metastatic) may be relevant to select an appropriate salvage strategy. Clinicians should be aware that the yield of some modalities (e.g., bone scan) is extremely low in patients with PSA values below 10 ng/ml.

Local recurrence. Overall, the decision regarding which modality to use to determine the presence or absence of local recurrence will depend on the availability of specific modalities and on the clinician's goals for imaging.

Recurrence in nodes. Overall, the Panel concluded that insufficient data are available to recommend specific techniques for the detection of recurrence in nodes.

Recurrence in bone. The yield of bone scans, given that most patients manifest biochemical failure at PSA values <1.0 ng/ml, will be low.

Metastatic recurrence. In the absence of multiple studies assessing each modality, definitive conclusions regarding the best imaging strategy to detect metastatic recurrence are not possible, but these data suggest that ^{11}C-choline positron emission tomography (PET)/computed tomography (CT), ^{18}F-fluoro-deoxyglucose (^{18}FDG) PET, and ^{18}F- fluoromethylcholine (^{18}FCH) PET/CT are promising.

Recurrence at all sites. Given the body of data on ^{11}C choline PET/CT, this imaging strategy appears promising. The probability of a positive scan, however, may depend on PSA level and PSA dynamics.

Guideline Statement 7

Physicians should offer salvage radiotherapy (SRT) to patients with PSA or local recurrence after RP in whom there is no evidence of distant metastatic disease. Recommendation

Discussion. (Evidence strength – Grade C; Benefits outweigh risks/burdens). In the context of administering SRT, clinicians should be aware that a large number of observational studies have reported that patients in certain high-risk groups have poorer outcomes than patients without these risk factors or in lower risk groups. As a group, these studies focused primarily on biochemical recurrence-free survival.

The panel notes that many considerations are important in the decision to administer SRT. As PSA recurrence may be noted years after RP, patients with limited life expectancy and a low or slowly-increasing PSA may have limited benefit from SRT. Other considerations may include sexual, gastrointestinal, or urinary function at the time of biochemical recurrence.

Guideline Statement 8

Patients should be informed that the effectiveness of RT for PSA recurrence is greatest when given at lower levels of PSA. Clinical Principle

Discussion. Patients should be advised that if recurrence is detected without evidence of distant metastases, then RT should be administered at the earliest sign of PSA recurrence and, ideally, before PSA rises to 1.0 ng/ml.

Guideline Statement 9

Patients should be informed of the possible short-term and long-term urinary, bowel, and sexual side effects of RT as well as of the potential benefits of controlling disease recurrence. Clinical Principle

Discussion. Patient counseling regarding the potential toxicity and quality of life impact of RT is important to ensure that patients make informed treatment decisions and have appropriate expectations regarding the course and consequences of RT. Counseling should include the fact that the evidence base for toxicity and quality of life (QoL) effects of RT is based mostly on reports using older RT techniques; newer techniques appear to have fewer toxic effects.

Acute toxicity. Patients should be informed that during RT and in the immediate post-RT period of 2-3 months, mild to moderate genitourinary and gastrointestinal effects that may require the use of medication for management have been frequently reported, with over 90% of patients experiencing these effects in some studies. Serious toxicity effects of RT, including those requiring aggressive medication management, outpatient procedures, or hospitalization, however, are uncommon or rare, with most studies reporting rates of 5% or less. The lowest acute toxicity rates have been reported with use of intensity-modulated radiotherapy (IMRT) radiotherapy techniques.

Late toxicity. Patients should be informed that, similar to acute toxicities, mild to moderate late toxicities occurring more than 90 days post-RT are commonly reported with some studies reporting rates as high as 79%. Serious late toxicities, however, are relatively uncommon, with most studies reporting rates of 10% or less. Patients also should be told that in a small proportion of patients, late toxicities that are moderate to major may emerge for up to four to five years post-RT and may persist beyond that point. These toxicities are more likely to include genitourinary symptoms

(up to 28% of patients) than to include gastrointestinal symptoms (up to 10.2% of patients). The use of newer RT techniques such as IMRT, however, is associated with lower cumulative rates of late genitourinary (up to 16.8% of patients) and gastrointestinal (4.0% of patients) toxicities.

Urinary incontinence. Patients should be informed that rates and severity of urinary incontinence in patients who have had RP and then ART are generally similar to rates for patients who have had RP only. Studies of SRT patients indicate possible mild worsening of urinary incontinence in small numbers of patients and isolated cases of new onset urinary incontinence. Overall, the Panel interpreted these data to indicate that RT is unlikely to have a major impact on urinary incontinence.

Sexual function. Patients with intact erectile function post-RP should be informed that the impact of RT on erectile function in men who have already had a prostatectomy is not clear. This uncertainty derives from the fact that few studies have addressed the impact of RT on erectile function in post-RP patients and also from the fact that most men post-RP do not have intact erectile function, making it difficult to determine whether RT results in further loss of function.

Adjuvant RT may reduce the need for salvage therapies. Patients also should be informed that the use of ART, because it is associated with improved biochemical recurrence-free survival compared to RP only, is likely to reduce the need for subsequent salvage therapies. Salvage therapies such as androgen deprivation can have debilitating side effects and also present increased risks for osteoporosis, cardiovascular disease, and other health problems.

Secondary malignancies. Clinicians should advise patients that the potential for developing secondary malignancies exists when postoperative RT is given, but that studies investigating the risk of developing secondary malignancies in men undergoing prostate cancer RT are contradictory. Furthermore, in clinical trials of adjuvant and salvage radiotherapy no data have been reported on secondary malignancies. Finally, the risk of secondary cancers may be related to co-existing behavioral factors such as the presence of past or current smoking. Therefore, the Panel concluded that at this time the risk of developing a secondary malignancy as a result of ART or SRT administration is not known.

Definitions:

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies with consistent findings

Grade C: Observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

American Urological Association Education and Research, Inc. (AUA) Nomenclature Linking Statement Type to Level of Certainty and Evidence Strength

Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A (high quality; high certainty) or B (moderate quality; moderate certainty) evidence

Recommendation: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C (low quality; low certainty) evidence

Option: Non-directive statement that leaves the decision regarding an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears equal or appears uncertain based on Grade A (high quality; high certainty), B (moderate quality; moderate certainty), or C (low quality; low certainty) evidence

Clinical Principle: A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature

Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Prostate cancer

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Oncology

Radiation Oncology

Radiology

Surgery

Urology

Intended Users

Physicians

Guideline Objective(s)

To provide a clinical framework for the use of radiotherapy after prostatectomy in patients with and without evidence of prostate cancer recurrence

Target Population

Patients with or without evidence of prostate cancer recurrence who have undergone prostatectomy

Interventions and Practices Considered

1. Counseling patients concerning risks of cancer recurrence after radical prostatectomy and benefits and risks of adjuvant radiotherapy (ART)
2. Offering patients ART after prostatectomy
3. Monitoring prostatic specific antigen (PSA) levels after prostatectomy to detect recurrence

4. Restaging evaluation in patients with a PSA recurrence
5. Offering salvage radiotherapy (SRT) to patients with PSA or local recurrence
6. Informing patients about effectiveness of radiotherapy for PSA recurrence
7. Informing patients about benefits and short- and long-term side effects of SRT for controlling disease recurrence

Major Outcomes Considered

- Rates of biochemical, local, and metastatic disease recurrence
- Rate of clinical progression of cancer
- Survival (including overall, biochemical recurrence-free, hormonal therapy-free, clinical progression-free, cancer-specific)
- Treatment failure (locoregional, metastatic, and biochemical)
- Need for salvage therapy
- Association of prostatic specific antigen (PSA) (levels or doubling time) with disease recurrence or mortality
- Treatment toxicity
- Death from prostate cancer
- Quality of life
- Sensitivity, specificity, and diagnostic performance of tests to detect disease recurrence
- Treatment toxicity

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A systematic review was conducted to identify published articles relevant to the use of radiotherapy after prostatectomy, including its efficacy in patients with detectable and undetectable prostatic specific antigen (PSA) levels, its toxicity and quality of life impact, and optimal imaging strategies to determine the appropriateness of radiotherapy use in patients suspected of recurrence. Literature searches were performed on English-language publications using the PubMed, Embase, and Cochrane databases from 1/1/1990 to 12/15/2012. Data from studies published after the literature search cut-off will be incorporated into the next version of this guideline. Preclinical studies (e.g., animal models), commentary, and editorials were excluded. Only studies in which PSA data were provided for 75% or more patients were included. Review article references were checked to ensure inclusion of all possibly relevant studies. Multiple reports on the same patient group were carefully examined to ensure inclusion of only nonredundant information.

Number of Source Documents

The review yielded an evidence base of 324 articles from which to construct a clinical framework for the use of radiotherapy after prostatectomy.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Body of Evidence Strength

Grade A: Well-conducted and highly-generalizable randomized controlled trials (RCTs) or exceptionally strong observational studies with consistent findings

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies with consistent findings

Grade C: Observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data

Note: By definition, Grade A evidence is evidence about which the Panel has a high level of certainty, Grade B evidence is evidence about which the Panel has a moderate level of certainty, and Grade C evidence is evidence about which the Panel has a low level of certainty.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Quality of Individual Studies and Determination of Evidence Strength

Quality of individual studies that were randomized controlled trials or controlled clinical trials was assessed using the Cochrane Risk of Bias tool. Case-control studies and comparative observational studies were rated using the Newcastle-Ottawa Quality (NOQ) Assessment Scale. Because there is no widely-agreed upon quality assessment tool for single cohort observational studies, the quality of these studies was not assessed except in the case of diagnostic accuracy studies. Diagnostic accuracy studies were rated using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS).

The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes consideration of study design, individual study quality, consistency of findings across studies, adequacy of sample sizes, and generalizability of samples, settings, and treatments for the purposes of the guideline. The American Urological Association (AUA) categorizes body of evidence strength as described in the "Rating Scheme for the Strength of the Evidence" field.

Limitations of the Literature

The Panel proceeded with full awareness of the limitations of the radiotherapy after prostatectomy literature. A major limitation of this literature is the lack of a large number of randomized controlled trials to guide decision-making in patients with and without evidence of recurrence and to indicate the appropriate use of androgen deprivation therapies in these patients. Further, a major limitation of all randomized trials in localized prostate cancer with long-term follow-up is the change in characteristics of contemporary patients; because of increased prostate cancer screening via prostatic specific antigen (PSA) testing and consequent detection of disease and initiation of therapy at earlier disease stages, patients recruited into trials decades ago have a greater risk of adverse outcomes than do contemporary patients. However, the Panel is fully aware that these issues will always be present in trials of therapies for localized prostate cancer because disease events (e.g., metastases and death) generally occur one to two decades after treatment.

Additional limitations include: the preponderance of non-randomized studies; poorly-defined or heterogeneous patient groups; in studies that compared radiotherapy (RT) administered to patients with and without recurrence, the lack of group equivalence in terms of pathological risk factors; variability in PSA assay sensitivity and in failure criteria across studies and over time; heterogeneity of cumulative radiation dose, dose schedules, methods of administering radiation, and treatment planning protocols; the paucity of studies with follow-up duration longer than 60 months; and, the overwhelming focus of the literature on biochemical recurrence with less information available regarding metastatic recurrence, cancer-specific survival, and overall survival. In addition, relatively few studies focused on quality of life outcomes that are of critical importance to patients, such as voiding and erectile function.

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

The Radiotherapy after Prostatectomy Panel was created in 2011 by the American Urological Association Education and Research, Inc. (AUA) and the American Society for Radiation Oncology (ASTRO). The AUA Practice Guidelines Committee and the ASTRO Guidelines Committee selected the Panel Chairs and the additional panel members with specific expertise in this area.

The mission of the committee was to develop recommendations that are analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the diagnosis and treatment of prostate cancer.

AUA Nomenclature: Linking Statement Type to Evidence Strength

The AUA nomenclature system explicitly links statement type to body of evidence strength, level of certainty, and the Panel's judgment regarding the balance between benefits and risks/burdens. See the "Rating Scheme for the Strength of the Recommendations" for details.

For some clinical issues, there was little or no evidence from which to construct evidence-based statements. Where gaps in the evidence existed, the Panel provides guidance in the form of *Clinical Principles* or *Expert Opinion* with consensus achieved using a modified Delphi technique if differences of opinion emerged. A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence.

Rating Scheme for the Strength of the Recommendations

American Urological Association Education and Research, Inc. (AUA) Nomenclature Linking Statement Type to Level of Certainty and Evidence Strength

Standard: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade A (high quality; high certainty) or B (moderate quality; moderate certainty) evidence

Recommendation: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C (low quality; low certainty) evidence

Option: Non-directive statement that leaves the decision regarding an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears equal or appears uncertain based on Grade A (high quality; high certainty), B (moderate quality; moderate certainty), or C (low quality; low certainty) evidence

Clinical Principle: A statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature

Expert Opinion: A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The American Urological Association Education and Research, Inc. (AUA) and the American Society for Radiation Oncology (ASTRO) conducted a thorough peer review process. The draft guidelines document was distributed to 75 peer reviewers, of which 44 reviewers provided comments. The panel reviewed and discussed all submitted comments and revised the draft as needed. Once finalized, the guideline was submitted for approval to the AUA Practice Guidelines Committee and the ASTRO Guidelines Committee. Then it was submitted to the AUA and ASTRO Boards of Directors for final approval.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendation and the nomenclature used for guideline statements is linked to evidence strength (see the "Major Recommendations" field).

The strategies and approaches recommended in this document were derived from evidence-based and consensus-based processes.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of adjuvant and salvage radiotherapy after prostatectomy

Potential Harms

- A key concern of clinicians and patients when adjuvant or salvage radiotherapy (RT) is contemplated is the toxicity and quality of life effects of RT in patients who have already undergone prostatectomy. The Panel's systematic review retrieved the literature relevant to these issues; findings are reviewed in the original guideline document in the section on "Toxicity and Quality of Life (QoL) Impact of RT Post-prostatectomy."
- Patients should be informed of the possible short-term and long-term urinary, bowel, and sexual side effects of RT as well as of the potential benefits of controlling disease recurrence. See Guideline Statement 9 in the "Major Recommendations" field for details on risks for acute toxicity, late toxicity, salvage therapy toxicity, urinary incontinence, sexual function, and secondary malignancies.
- The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions, and warnings.

Qualifying Statements

Qualifying Statements

- While these guidelines do not necessarily establish the standard of care, the American Society for Radiation Oncology (ASTRO) and the American Urological Association Education and Research, Inc. (AUA) seek to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. Furthermore, this Guideline should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment and propriety of any specific therapy must be made by the physician and the patient in light of all the circumstances presented by the individual patient. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.
- Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ("off label") that are not approved by the US Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. ASTRO/AUA urges strict compliance with all government regulations and protocols for prescription

and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions, and warnings. These guidelines and best practice statements are not intended to provide legal advice about use and misuse of these substances.

- The strategies and approaches recommended in this document were derived from evidence-based and consensus-based processes. This document constitutes a clinical strategy and is not intended to be interpreted rigidly. The most effective approach for a particular patient is best determined by discussions among the multidisciplinary team of physicians, the patient, and his family. As the science relevant to the use of radiotherapy after prostatectomy evolves and improves, the strategies presented here will require amendment to remain consistent with the highest standards of clinical care.
- ASTRO/AUA assumes no liability for the information, conclusions, and findings contained in the Guideline.
- Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited and are prepared on the basis of information available at the time the panel was conducting its research on this topic. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by this Guideline as necessarily experimental or investigational. In addition, this Guideline cannot be assumed to apply to the use of these interventions performed in the context of clinical trials, given that clinical studies are designed to evaluate or validate innovative approaches in a disease for which improved staging and treatment are needed or are being explored.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Valicenti RK, Thompson I Jr, Albertsen P, Davis BJ, Goldenberg SL, Wolf JS, Sartor O, Klein E, Hahn C, Michalski J, Roach M III, Faraday MM. Adjuvant and salvage radiotherapy after prostatectomy: AUA/ASTRO guideline. Fairfax (VA): American Society for Radiation Oncology (ASTRO); 2013 Apr. 82 p. [334 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Apr

Guideline Developer(s)

American Society for Radiation Oncology - Professional Association

American Urological Association Education and Research, Inc. - Medical Specialty Society

Source(s) of Funding

American Society for Radiation Oncology (ASTRO) and the American Urological Association Education and Research, Inc. (AUA)

Guideline Committee

The Radiotherapy after Prostatectomy Panel

Composition of Group That Authored the Guideline

Panel Members: Richard K. Valicenti, M.D., M.B.A., Department of Radiation Oncology, University of California, Davis School of Medicine; Ian Thompson Jr., M.D., Department of Urology, University of Texas Health Science Center at San Antonio; Peter Albertsen, M.D. M.S., Division of Urology, University of Connecticut Health Center; Brian J Davis, M.D., Ph.D., Department of Radiation Oncology, Mayo Medical School; S. Larry Goldenberg, M.D., Department of Urologic Sciences, University of British Columbia; J. Stuart Wolf M.D, Department of Urology, University of Michigan; Oliver Sartor, M.D., Department of Medicine and Urology, Tulane Medical School; Eric Klein, M.D., Glickman Urological Kidney Institute, Cleveland Clinic; Carol Hahn, M.D., Department of Radiation Oncology, Duke University Medical Center; Jeff Michalski, M.D., M.B.A., Department of Radiation Oncology, Washington University School of Medicine; Mack Roach III, M.D., Department of Radiation Oncology, University of California, San Francisco; Martha M Faraday, Ph.D., Four Oaks, Inc.

Financial Disclosures/Conflicts of Interest

Before initiation of this guideline all members of the guideline panel were required to complete disclosure statements. These statements are maintained at the American Society for Radiation Oncology (ASTRO) Headquarters in Fairfax, VA and pertinent disclosures are published with the report. The ASTRO Conflict of Interest (COI) Disclosure Statement seeks to provide a broad disclosure of outside interests. Where a potential conflict is detected, remedial measures to address any potential conflict were taken and noted in the disclosure statement. Dr. Mack Roach is a consultant for Astra-Zeneca, Astellas, CareCore, Darden Associates, Ferring Pharma, Mayo Foundation, and MCIC Vermont Inc. Dr. Oliver Sartor is a consultant for Algeta, Amgen, Astra- Zeneca, Bayer Pharmaceuticals, Bellicum, Bristol-Myers Squibb, Celegene, Cougar, Dendreon, Exelixis, Glaxo-Smith Kline, Johnson & Johnson, Medivation, Oncogenex, Sanofi, and Takeda. Dr. Carol Hahn is a member of the American Society for Radiation Oncology Board of Directors. Dr. Brian Davis is the Co-chair, Prostate Brachytherapy School, for the American Brachytherapy Society. Dr. Eric Klein has received research funding from Varian. Dr. Stuart Wolf is Chair, Practice Guidelines Committee for the American Urological Association. The guideline panel chairs reviewed these disclosures and determined that they do not present a conflict with respect to these panel members' work on this guideline.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the American Society for Radiation Oncology Web site .

Availability of Companion Documents

The following is available:

- Adjuvant and salvage radiation therapy after prostatectomy: American Society for Radiation Oncology/American Urological Association guidelines. CME course. Available from the American Society for Radiation Oncology Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 1, 2013. The information was verified by the guideline developer on September 12, 2013.

Copyright Statement

Disclaimer

NGC Disclaimer